

## **REMARKS**

Upon entry of the present amendments, claims 1, 2, 40, and 66 will be pending in the application. Claims 6-39 and 41-65 have been cancelled as drawn to a non-elected invention. Claims 3-5 have also been cancelled. Claims 1 and 2 have been amended. The amendments to claim 1 are supported by disclosure at page 14, lines 36-39, of the specification. The amendments to claim 2 and new claim 66 are supported by disclosure at page 3, lines 11-14 and at page 123, lines 17-20, of the specification. No new matter has been added by the amendments.

The pending claims have been objected to and/or rejected for various reasons. Each will be addressed individually below.

### **Formal Matters:**

#### **Specification**

The Examiner has objected to the specification due to informalities. First, page 11, line 17 indicates “(see Table 6)”, whereas there is no Table 6. This paranthetical should indicate “(see Table 3)”, and the specification has been so amended herein. Second, at page 123, line 17, “the *two* bands” should be “the *three* bands”. As suggested by the Examiner, the specification has been amended to rectify this discrepancy.

#### **Claims**

The Examiner has objected to claim 5 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 5 has been cancelled. Therefore, this objection is moot and should be withdrawn.

### **Objections and Rejections:**

#### **Rejection under 35 U.S.C. §112, second paragraph**

Claims 1-5 and 40 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner asserts that claim 1 is indefinite for reciting “a mature form”, “a variant”, and “a fragment”. Claim 1 has been amended herein to comprise an amino acid sequence of SEQ ID NO:4. Applicants assert that claim 1, as amended, is clear and definite. Furthermore, claim 40 depends from claim 1. Applicants contend that the amendment to claim 1, renders claims 1 and 40 clear and definite.

The Examiner also asserts that claim 2 is indefinite and confusing for reciting “a FCTR2 fragment of a FCTR2 polypeptide”. Claim 2 has been amended herein to recite particular fragments of FCTR2, *i.e.*, amino acid residues 247-370 of SEQ ID NO:2, amino acid residues 247-338 of SEQ ID NO:2, and amino acid residues 339-370 of SEQ ID NO:2. Therefore, Applicants contend that claim 2, as amended, is clear and definite.

The remaining claims 3-5 have been cancelled. Therefore, the rejection as applied to these claims is moot.

In view of the amendments discussed above, Applicants request that the §112 indefiniteness rejections be withdrawn.

### **Rejection under 35 USC §112, first paragraph**

Claims 1-5 and 40 have been rejected under 35 USC §112, first paragraph, for allegedly lacking enablement for the scope of the claims that encompass SEQ ID NO: 4, fragments, and variants thereof.

The Examiner has acknowledged that the specification is enabling for a dimer (p35) formed by bands I, II, and/or III, wherein bands I-III represent three specific fragments of SEQ ID NO:4 (or SEQ ID NO:2), *i.e.*, band I is 22-25 kDa with N-terminal beginning at residue 247 of SEQ ID NO:2, band II is about 16 kDa with N-terminal beginning at residue 247 of SEQ ID NO:2, and band III is about 5-6 kDa with N-terminal beginning at residue 339 of SEQ ID NO:2. However, the Examiner asserts that the specification does not reasonably provide enablement for claims to SEQ ID NO:4, variants, and fragments thereof because the specification does not teach that SEQ ID NO:4, variants, or fragments thereof have any biological function equivalent to that of p35 protein. Applicants traverse.

Claim 1 has been amended to delete references to fragments and variants. Claim 2 has been amended to recite particular fragments of FCTR2, *i.e.*, amino acid residues 247-370 of SEQ

ID NO:2, amino acid residues 247-338 of SEQ ID NO:2, and amino acid residues 339-370 of SEQ ID NO:2. Claims 3-5 have been cancelled. Claim 40 depends from claim 1 and incorporates these changes by reference. Accordingly, the enablement rejections pertaining to fragments and variants are rendered moot as the claims no longer recite fragments and variants.

Regarding SEQ ID NO:4, the Examiner acknowledges on pages 2-3 of the instant Office Action that utility has been shown for claims 1-5 and 40 because “the p35 FCTR protein is demonstrated to have specific biological activities, such as binding and phosphorylation of the PDGF-alpha receptor (Ex 14) and that the p35 fragments have been verified to be cleaved products and are encompassed within SEQ ID NO:4 (Ex 12).” Accordingly, since the sequence of SEQ ID NO:4 has been disclosed in the application and since utility for it has been established, a skilled artisan would not require undue experimentation to practice the invention as claimed. Applicants respectfully submit, therefore, that the claims are enabled.

The Examiner has also asserted that the specification provides no guidance as to how to use an inactive polypeptide of SEQ ID NO:4 because no functional limitation is associated with the claimed polypeptides. Claim 1, as amended herein, is drawn to a polypeptide having growth factor activity. Thus, Applicants contend that the claims are fully enabled and respectfully request that the enablement rejections be withdrawn.

### **Written Description**

The Examiner has also rejected claims 1-5 and 40 under 35 USC §112, first paragraph for allegedly lacking adequate description to reasonably convey to persons of ordinary skill in the art that, at the time the application was filed, the inventors had possession of the claimed invention. The Examiner acknowledges that the specification satisfies the written description requirement for two amino acid sequences, FCTR1 and FCTR2 (SEQ ID NO: 2 and 4, respectively) and for the three specific fragments of SEQ ID NO:4 (referred to as bands I-III).

As discussed previously, claim 1 has been amended to recite only to SEQ ID NO:4 having growth factor activity. Moreover, claim 2 has been amended to specifically refer to the three fragments of SEQ ID NO:4 described as band I, II, and III. Claims 3-5 have been cancelled and claim 40 depends from claim 1. Therefore, Applicants contend that the specification contains adequate written description for the claims as amended. Thus, this rejection should be

withdrawn.

### **Rejection under 35 U.S.C. § 102**

Claims 1-5 and 40 were rejected as being anticipated by Eriksson *et al*, WO 00/27879. According to the Examiner, Eriksson *et al*. disclose a human platelet derived growth factor, PDGF-D (SEQ ID NO:6 or 8), comprising the amino acid sequence of SEQ ID NO:4 of the present invention with 100% identity. In addition, Eriksson *et al*. disclose fragments and various variants including a naturally-occurring allelic variant with a single nucleotide variation, and a polypeptide variant comprising one or more conservative amino acid substitutions. Applicants traverse.

Claim 1 recites SEQ ID NO:4, which is a 132 amino acid polypeptide that corresponds to amino acids 239-370 of SEQ ID NO:2 of the present application. SEQ ID NO:4 is a piece of, and is not the exact same sequence as, either SEQ ID NO:6 (322 amino acids) or SEQ ID NO:8 (370 amino acids) as disclosed by Eriksson *et al*. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with “sufficient specificity to constitute an anticipation under the statute.” *See* MPEP § 2131.03. What constitutes a “sufficient specificity” is fact dependent. *Id*. In this case, claim 1 is directed to a very specific polypeptide of SEQ ID NO:4. This specific fragment has specific activity, as shown in Examples 12 and 14 of the specification. As the Examiner has acknowledged, this specific fragment “is demonstrated to have specific biological activities, such as binding and phosphorylation of the PDGF-alpha receptor (Ex 14) and that the p35 fragments have been verified to be cleaved products and are encompassed within SEQ ID NO:4 (Ex 12).” Neither the longer polypeptides nor the fragments (amino acids 255-370 and amino acids 235-370 of SEQ ID NO:8) disclosed by Eriksson *et al*. have been demonstrated to have these same activities. These sequences, therefore, do not adequately describe or predict the specific polypeptide of SEQ ID NO:4. Therefore, Applicants assert that the claims, as amended herein, are novel and this rejection should be withdrawn.

**Conclusion**

It is submitted that the application is in condition for allowance, and such action is respectfully requested. A petition for extension of time is enclosed with this response. With this petition, this response is due on or before February 27, 2003.

Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below. The Commissioner is authorized to charge any additional fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311, Ref. No. 15966-577.

Respectfully submitted,

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